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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,335	07/25/2005	Laurent Cavarec	G-194US03PCT	9318

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1649	
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05/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,335	CAVAREC ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-60,62,63 and 87-89* is/are pending in the application.

4a) Of the above claim(s) *53,62,63,88 and 89* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-52,54-60 and 87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No._____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/26/6*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 50-52, 54-60 and 87, polypeptide of SEQ ID NO: 2, in the reply filed on March 27, 2007 is acknowledged.

Claims 53, 62, 63, 88 and 89 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 27, 2007.

Claims 50-52, 54-60 and 87 are under examination in the instant office action.

Information Disclosure Statement

2. The information disclosure statement filed on January 26, 2006 fails to comply with 37 CFR 1.98(b)(5), which requires the following:

(b)(5) Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.

The information disclosure statement filed on January 26, 2006 has been considered in part (See MPEP § 609).

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 50-52, 54-60 and 87 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

It is clear from the instant application that the protein described therein is what is termed an "orphan protein" in the art. The DNA of the instant application has been isolated because of its similarity to a known DNA. There is little doubt that, after complete characterization, this DNA and encoded protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a

patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to an isolated nucleic acid molecule and the protein encoded thereby of as yet undetermined function or biological significance. It is clear from the instant specification that the claimed nucleic acid encodes a novel protein KCNQ2-15b of SEQ ID NO: 2, which belongs to the potassium channel family of proteins (pp. 1 and 10 of the instant specification). More specifically, "KCNQ2 was first cloned in 1996. [...] a five-base pair insertion deleting more than 3000 amino acids from the carboxyl-terminus of KCNQ2 leads to impairment of potassium-selective currents *in vitro*. It was thus demonstrated that loss of function mutations in KCNQ2 causes the epileptic syndrome" (p 2 of the specification). Thus, the KCNQ2 gene is known in the art and has been reported to be associated with certain pathological conditions. The instant polypeptide of SEQ ID NO: 2 is asserted to be a subunit of a potassium channel based on its structural similarity to the KCNQ2 family of proteins (see Fig. 1 and 2, description at p. 12). However, the instant specification fails to disclose any specific biological activity of this instant novel protein of SEQ ID NO: 2 or its significance to a clinical condition or any other practical use of the KCNQ2-15b polypeptide or encoding polynucleotide.

In the absence of knowledge of the biological significance of this specific nucleic acid and encoded protein, there is no immediately obvious patentable use for the polynucleotide or the encoded protein. According to the specification of the instant application "KCNQ2-15b polypeptides are capable of binding to the Bγ subunit of the PP2A phosphatase" (middle at p. 18 of the specification), and that KCNQ2 polypeptides can be used "as a target for screening candidate modulators" (bottom at p. 29). However, the instant specification fails to provide any evidence or sound scientific reasoning that would support a conclusion that the instant nucleic

acid or encoded protein is associated with any diseases or disorder. To employ the DNA and the protein in the future methods "for testing modulators for their ability to increase or decrease the activity of a KCNQ2 polypeptide or to increase or decrease the expression of a KCNQ2 mRNA" (middle at p. 30) is not a "real world" because it would eventually relate to a protein for which no biological function is known.

Because the instant specification does not teach a biological activity of the protein, which supports a practical utility, one would not reasonably believe that the administration of a modulator of the activity of KCNQ2-15b polypeptide of SEQ ID NO: 2, such activity not currently disclosed, would prevent or treat a condition or disease, like bipolar disorder, schizophrenia and depression, as implied by the specification. To employ a nucleic acid of the instant invention in any of the disclosed methods would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the encoded protein in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 50-52, 54-60 and 87 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial

credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 50-52, 54-60 and 87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 50, 52, 55 and 87 are vague and indefinite for recitation of a polypeptide or a polynucleotide "comprising SEQ ID NO:". Applicant is advised that "SEQ ID NO:" is a sequence identifier, which is a characteristic of the structure of a molecular embodiment and not a part of it. As such, the limitation is indefinite because it is not clear how a molecule could comprise an identifier. Using limitation "a polypeptide comprising amino acid sequence of SEQ ID NO: 2", or "a polynucleotide of SEQ ID NO: 1", for example, would obviate this ground of rejection.

10. Claim 57 is vague and indefinite for recitation "a gene therapy vector". The metes and bounds of the recitation cannot be determined from the claim or the instant specification, as filed. If the claim intends to limit the vector of claim 56 only to the vectors to be used for gene therapy purposes, then the claimed subject matter raises the issues of possible lack of enablement of the claimed invention.

11. Claim 59 is vague and ambiguous for recitation "a polypeptide". Specifically, claim 59 depends from claim 58, which recites a host cell. It is obvious that the host cell of claim 58

expresses plurality of polypeptides not limited to the polypeptide encoded by a polynucleotide of SEQ ID NO: 1. Therefore, it is not clear a method of making what polypeptide is intended by the claim. Moreover, since claim 59 depends from claim 54, which recites complimentary nucleic acid sequences, the instant claimed method, if limited to the making of polypeptide of SEQ ID NO: 2, is lacking enablement. Clarification is required.

12. Claims 51, 54, 56, 58, 60 and 87 are indefinite for being dependent from indefinite claims.

Double Patenting

13. Applicant is advised that should claim 50 be found allowable, claim 51 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, claim 51 recites the ability of the polypeptide of SEQ ID NO: 2 to bind PP2A phosphatase. Unless there are specific structural limitations that define this binding ability, the scope of two claims appears to be identical.

Allowable Subject Matter

14. At pp. 58-63, the instant specification discloses specific markers that appear to be useful for diagnosis of bipolar disorder. The relationship between the markers and the instant claimed polynucleotide encoding polypeptide of SEQ ID NO: 2 is not apparent; however, if

polynucleotide of SEQ ID NO: 1 contains any markers that are diagnostic of a pathological condition, then the invention which recites these specific markers would meet the utility requirement under 35 U.S.C. 101.

Conclusion

15. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.

Primary Examiner
Art Unit 1649

April 30, 2007